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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,567	09/19/2005	Peter Mullejans	P70821US0	9658
136	7590	04/01/2009	EXAMINER	
JACOBSON HOLMAN PLLC			HAND, MELANIE JO	
400 SEVENTH STREET N.W.				
SUITE 600			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20004			3761	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/549,567	MULLEJANS ET AL.
	Examiner	Art Unit
	MELANIE J. HAND	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 December 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed December 10, 2008 have been fully considered but they are moot in view of the new grounds of rejection prompted by applicant's amendment to the claims. However examiner will address the essence of applicant's arguments herein. With respect to arguments regarding claims 1, 7 and 12, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the recited receiving bag is reusable or reused, and that the inner bag liner is exchanged with a fresh inner bag) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The outer bag of Smith is water-impermeable and thus by its nature reusable regardless of whether the intent is to dispose of it or not. The limitation regarding exchanging the inner bag liner with a fresh new bag is in claim 2, not claim 1, therefore applicant's argument with regard to claim 1 that, in the article of Smith there is no need to leave the inner bag liner folded if the outer bag is not reusable is moot.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the term "inner bag liner bottom portion" now recited in the independent claims 1, 7, 12 and 14 as amended lacks antecedent basis in the specification.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-4, 6-10 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (U.S. Patent No. 5,591,144).

With respect to **claim 1**: The term "distal" and phrase "most distal" are not clearly and explicitly disclosed, as it is unclear from the disclosure what the structural feature of concern is distal or most distal in comparison to. Thus, claim 1 is given its broadest reasonable interpretation herein. Smith teaches an ostomy appliance comprising: a base plate in the form of flange 3, said base plate having a first hole for receiving a stoma and an adhesive wafer in the form of adhesive layer 4 having a first surface to be attached to the wearer's abdomen, back, or chest (Fig. 5). A receiving member/bag 1 is releasably and reattachably attached to the base plate 3 via double sided tape 12, said receiving member/bag 1 having a second hole for receiving

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wastes exiting the stoma and a receiving bag bottom portion that is considered herein to define a distal-most part of said receiving bag relative to said second hole. It is examiner's position that the receiving bag bottom portion defines said distal-most point relative to said second hole because the bottom portion is located at a point where it cannot extend any farther away from the second hole. (Fig. 2) A disposable inner bag liner 2 forms a second bag inside the receiving member 1 and is attachable to the base plate 3 in a first coupling area by a first coupling component. The disposable inner bag liner 2 has a third hole for receiving wastes exiting the stoma and the receiving member 1 is releasably and reattachably attachable to the base plate 3 by a second coupling component. The first coupling component is in the form of a flange projecting from the rim of the third hole (indicated generally at item 2a in Fig. 2A) and having a surface for sealing via welding against a second surface of the base plate 3 facing away from the user. Inner bag liner 2 has folds along a plurality of folding lines such that said inner bag liner 2 is compacted lengthwise prior to use. The folds are provided between the third hole and an inner bag liner bottom portion that defines a distal-most part of the inner bag liner relative to said third hole. The inner bag liner bottom portion disclosed by Smith defines a distal-most position relative to the third hole both when the inner bag liner is folded and when the inner bag liner is fully unfolded inside the receiving bag to reach a most-distal position relative to said third hole so that the receiving member/bag is empty and in said compacted condition (as shown in Fig. 2 of Smith). The inner bag liner bottom portion disclosed by Smith is then in a folded position adjacent said third hole such that initial wastes exiting the stoma will push against said inner bag liner bottom portion as a result of gravity and the mass of the waste. This pushing force from the wastes will necessarily cause said folds disclosed by Smith to unfold so that said inner bag liner bottom portion moves away from said folded position adjacent said third hole to

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said distal-most position relative to said third hole, as the inner bag liner is filled due to physical force applied to the liner bottom from the flow of waste from the stoma. (Cols. 4 and 5, all lines)

Smith teaches that inner bag liner 2 is welded to base plate 3 (first coupling component) and thus does not teach that the bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling component. However, Smith teaches that welding and double sided adhesive tape are equivalent means for attaching outer bag 1 to the base plate 3.

Therefore, it would be obvious to one of ordinary skill in the art to modify the article of Smith such that bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling component, i.e. the adhesive flange projecting from the rim of said third hole, with a reasonable expectation of success to provide quicker releasable attachment of the disposable single-use bag liner 2. The first coupling component of the article fairly suggested by Smith has a surface for releasable sealing against a first surface of the adhesive wafer and is in the form of an adhesive flange.

With respect to **claim 2:** The second coupling component taught by Smith is in the form of an adhesive flange 12 of double sided adhesive tape projecting from the rim of the second hole and necessarily having a surface for adhesive sealing against the second surface of the base plate 3 opposite the surface adhered to the user. (Col. 4, lines 39-41) Thus, because the first and second coupling components meets all of the structural limitations of claim 1 and 2, the first and second coupling components are necessarily configured to allow the inner bag liner to be removed and replaced with a new inner bag liner while reusing the receiving bag.

With respect to **claim 3:** Smith does not teach that an outer diameter of the first coupling component is greater than an inner diameter of the second coupling component. However, increasing the length of said first coupling means (i.e. the flange in the marked Fig. 2A of Smith

shown below) such that the outer diameter is greater than the inner diameter of second coupling means 12 would provide more surface area for adhesion of bag liner 2 to base plate 3, thus providing more securement for the receiving member/bag while in use as the flow of exudates applies force to the bag liner, preventing the bag liner 2 from becoming prematurely detached. It would be obvious to one of ordinary skill in the art to modify the article of Smith so as the lengthen the adhesive flange of bag liner 2 projecting from the rim of said third hole such that the outer diameter of the flange, i.e. the first coupling component, is greater than the inner diameter of second coupling component 12 to provide stronger securement of the bag liner to the base plate to prevent premature detachment of the bag liner during use.

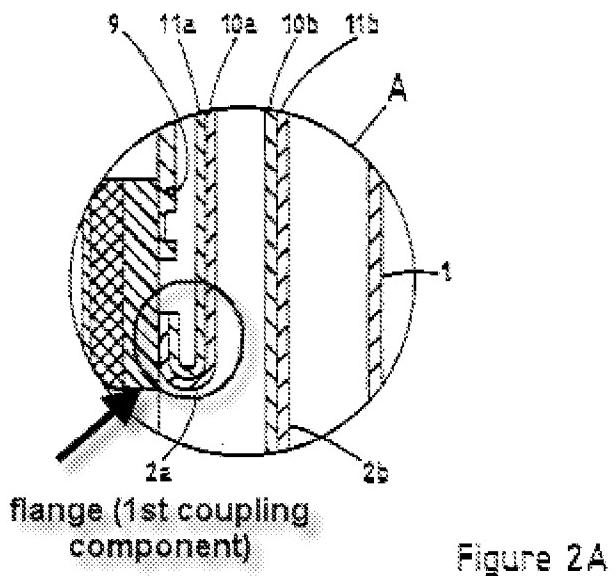


Figure 2A

With respect to **claim 4**: A peel strength of the adhesive sealing of the first coupling component taught by Smith is necessarily greater than a peel strength of the second coupling component, as Smith teaches double sided tape for the second component 12 (Col. 4, lines 39-41), which is a releasable means of coupling, whereas Smith teaches welding for the first coupling means

(Col. 4, lines 33-35), which is a permanent mechanical attachment and thus has a greater peel strength.

With respect to **claim 6**: The inner bag liner 2 taught by Smith is provided with a membrane in the form of discrete films laminated together that is permeable to flatus gases (Col. 3, lines 5,6) and thus allows intestinal gas to escape but is water-impermeable. (Col. 3, line 16)

With respect to **claim 7**: The term "distal" and phrase "most distal" are not clearly and explicitly disclosed, as it is unclear from the disclosure what the structural feature of concern is distal or most distal in comparison to. Thus, claim 7 is given its broadest reasonable interpretation. Smith teaches an ostomy appliance comprising an adhesive wafer in the form of adhesive flange 3, said adhesive wafer 3 having a first hole for receiving a stoma, said adhesive wafer 3 having a first surface to be attached to the wearer's abdomen, inasmuch as Smith refers to flatus gases, which are intestinal gases. A receiving bag 1 is attached to the adhesive wafer 3, said receiving bag 1 having a second hole for receiving wastes exiting the stoma and a receiving bag bottom portion that is considered herein to define a distal-most part of said receiving bag relative to said second hole. It is examiner's position that the receiving bag bottom portion defines said distal-most point relative to said second hole because the bottom portion is located at a point where it cannot extend any farther away from the second hole. (Fig. 2) A disposable inner bag liner 2 disclosed by Smith forms a second bag inside the receiving bag 1, said disposable inner bag liner 2 having a third hole for receiving wastes exiting the stoma is releasably attachable to the base plate 3 in a first coupling area by a first coupling component. The first coupling component is the form of a flange projecting from the rim of the third hole and has a surface for releasable sealing against a first surface of the adhesive wafer 3 inasmuch as Smith teaches that the bag

liner 2 is welded to the wafer 3 and has a first surface for sealing against a first surface of the adhesive wafer. Inner bag liner 2 has folds along folding lines such that said inner bag liner 2 is compacted lengthwise prior to use, said folds being provided between the third hole and a an inner bag liner bottom portion that defines a distal-most part of the inner bag liner relative to said third hole. The inner bag liner bottom portion disclosed by Smith defines a distal-most position relative to the third hole both when the inner bag liner is folded and when the inner bag liner is fully unfolded inside the receiving bag to reach a most-distal position relative to said third hole so that the receiving member/bag is empty and in said compacted condition (as shown in Fig. 2 of Smith). The inner bag liner bottom portion disclosed by Smith is then in a folded position adjacent said third hole such that initial wastes exiting the stoma will push against said inner bag liner bottom portion as a result of gravity and the mass of the waste. This pushing force from the wastes will necessarily cause said folds disclosed by Smith to unfold so that said inner bag liner bottom portion moves away from said folded position adjacent said third hole to said distal-most position relative to said third hole, as the inner bag liner is filled due to physical force applied to the liner bottom from the flow of waste from the stoma. (Cols. 4 and 5, all lines)

Smith teaches that inner bag liner 2 is welded to base plate 3 and thus does not teach that the bag liner 2 is reattachably attachable to the base plate 3 in a first coupling area by a first coupling component. However, Smith teaches that welding and double sided adhesive tape are equivalent means for attaching outer bag 1 to the base plate 3 and teaches that bag liner 2, not outer receiving member/bag 1, is disposed of after a single use, therefore it would be obvious to one of ordinary skill in the art to modify the article of Smith such that bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling component, i.e. the adhesive flange projecting from the rim of said third hole with a reasonable expectation of success to provide quicker releasable attachment of the disposable single-use bag liner 2. The

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first coupling component of the article fairly suggested by Smith thus has a surface for releasable and reattachable sealing against a first surface of the adhesive wafer and thus comprises an adhesive flange.

With respect to **claim 8**: Smith teaches that the inner bag liner when compacted lengthwise forms a disc-like structure having an outer diameter. (Figs. 2,4) Examiner's position regarding whether the structure is disc-like is based upon the fact that the structure is generally circular and flat. However, Smith does not teach that the outer diameter of the disc-like structure is less than the inner diameter of the first coupling component. However, this is achieved by merely changing the placement of the folds. Since the bag liner 2 is limited by its own size and the size of the outer receiving member/bag 1, there are only a finite number of fold placements that can be achieved such that the liner meets the remaining claim limitations and still fits within the receiving member/bag. Further, Smith teaches that bag liner 2 is disposable. The task of disposal of bag liner 2 would be made easier by a compacted bag liner 2 whose outer diameter when compacted is less than the inner diameter of the first coupling component and the third hole. This would mean that the bag liner 2 is unobstructed, and this configuration would facilitate easy grasping and pulling of the bag liner 2 out of the outer bag 1 for disposal. It would thus be obvious to one of ordinary skill in the art to modify the article of Smith such that the outer diameter of the disc-like structure of bag liner 2 when compacted has an outer diameter that is less than the inner diameter of said first coupling component so as to provide an unobstructed path for removal and disposal of a used bag liner 2.

With respect to **claim 9:** The folding of said liner 2 taught by Smith along said folding lines located generally at the flange of the bag liner attaching to the base plate forms a bellows. (Fig. 2)

With respect to **claim 10:** The folding of said liner 2 taught by Smith along said folding lines results in lengthwise compaction of the bag liner 2, thus necessarily forming a telescopic bellows, as the receiving member/bag 1 that it is compacted inside of unfolds lengthwise as well. (Figs. 2, 5, 6)

With respect to **claim 12:** The term "distal" and phrase "most distal" are not clearly and explicitly disclosed, as it is unclear from the disclosure what the structural feature of concern is distal or most distal in comparison to. Thus, claim 12 is given its broadest reasonable interpretation. Smith teaches a disposable inner bag liner 2 having an open end for receiving effluents or waste products of the body and for use together with an ostomy appliance having an adhesive wafer in the form of adhesive flange 3 to be attached to the wearer's abdomen. Examiner's position is based upon Smith's teaching of flatus gases, which are intestinal gases. A receiving bag 1 has a receiving bag hole for receiving wastes exiting the stoma. The disposable inner bag liner 2 comprises a liner hole in said open end for receiving wastes exiting the stoma, and has a closed end capable of forming a bag inside receiving bag 1. An adhesive flange projects from the rim of the liner hole (Fig. 2A) and has a surface for sealing against a first surface of the adhesive wafer 3 inasmuch as Smith teaches that the bag liner 2 is welded to the adhesive flange. Inner bag liner 2 has folds along folding lines such that said inner bag liner 2 is compacted lengthwise prior to use, said folds being provided between the liner hole and an inner bag liner bottom portion that defines a distal-most part of the inner bag liner relative to said

liner hole. The inner bag liner bottom portion disclosed by Smith defines a distal-most position relative to the third hole both when the inner bag liner is folded and when the inner bag liner is fully unfolded inside the receiving bag to reach a most-distal position relative to said liner hole so that the inner bag liner is empty and in said compacted condition (as shown in Fig. 2 of Smith). The inner bag liner bottom portion disclosed by Smith is then in a folded position adjacent said liner hole such that initial wastes exiting the stoma will push against said inner bag liner bottom portion as a result of gravity and the mass of the waste. This pushing force from the wastes will necessarily cause said folds disclosed by Smith to unfold so that said inner bag liner bottom portion moves away from said folded position adjacent said third hole to said distal-most position relative to said third hole, as the inner bag liner is filled due to physical force applied to the liner bottom from the flow of waste from the stoma. (Cols. 4 and 5, all lines)

Smith teaches that inner bag liner 2 is welded to base plate 3 and thus does not teach an adhesive flange that projects from the rim of the liner hole. However, Smith teaches that welding and double sided adhesive tape are equivalent means for attaching outer receiving member/bag 1 to the base plate 3 and teaches that bag liner 2, not outer receiving member/bag 1, is disposed of after a single use, therefore it would be obvious to one of ordinary skill in the art to modify the article of Smith such that an adhesive flange projects from the rim of said third hole with a reasonable expectation of success to provide quicker releasable attachment of the disposable single-use bag liner 2. The article fairly suggested by Smith thus discloses a surface for releasable sealing against a first surface of the adhesive wafer and thus comprises an adhesive flange that projects from the rim of the liner hole.

With respect to **claim 13:** The inner bag liner 2 taught by Smith is provided with a membrane comprised of water-impermeable material such as polyvinyl alcohol, which inherently and

necessarily allows intestinal gas to escape but is impermeable to liquids, as polyvinyl alcohol film is only gas-permeable.

With respect to **claim 14**: The term "distal" and phrase "most distal" are not clearly and explicitly disclosed, as it is unclear from the disclosure what the structural feature of concern is distal or most distal in comparison to. Thus, claim 14 is given its broadest reasonable interpretation herein. Smith teaches a method of applying to an ostomate an ostomy appliance comprising a base plate in the form of flange 3, said base plate having a first hole for receiving a stoma and an adhesive wafer in the form of adhesive layer 4 having a first surface to be attached to the wearer's abdomen. Examiner's position is based upon Smith's teaching of flatus gases, which are intestinal gases. A receiving bag 1 is releasably attachable to the base plate 3 via double sided tape 12, said receiving bag 1 having a second hole for receiving wastes exiting the stoma and a receiving bag bottom portion that is considered herein to define a distal-most part of said receiving bag relative to said second hole. It is examiner's position that the receiving bag bottom portion defines said distal-most point relative to said second hole because the bottom portion is located at a point where it cannot extend any farther away from the second hole. (Fig. 2) A disposable inner bag liner 2 forms a second bag inside the receiving bag 1 and is releasably attachable to the base plate 3. The disposable inner bag liner 2 has a third hole for receiving wastes exiting the stoma. Inner bag liner 2 is compacted lengthwise by folds along folding lines to form a disc-like structure. The folds are provided between the third hole and an inner bag liner bottom portion that defines a distal-most part of the inner bag liner relative to said third hole. The inner bag liner bottom portion disclosed by Smith defines a distal-most position relative to the third hole both when the inner bag liner is folded and when the inner bag liner is fully unfolded inside the receiving bag to reach a most-distal position relative to said third hole

so that, the receiving member/bag is empty and in said compacted condition (as shown in Fig. 2 of Smith). The inner bag liner bottom portion disclosed by Smith is then in a folded position adjacent said third hole such that initial wastes exiting the stoma will push against said inner bag liner bottom portion as a result of gravity and the mass of the waste. This pushing force from the wastes will necessarily cause said folds disclosed by Smith to unfold so that said inner bag liner bottom portion moves away from said folded position adjacent said third hole to said distal-most position relative to said third hole, as the inner bag liner is filled due to physical force applied to the liner bottom from the flow of waste from the stoma. (Cols. 4 and 5, all lines) The disposable inner bag liner 2 has a third hole for receiving wastes exiting the stoma and the receiving member 1 is releasably attachable to the base plate 3 by a second coupling component. The first coupling component is in the form of a flange projecting from the rim of the third hole (indicated generally at item 2a in Fig. 2A) and having a surface for sealing via welding against a second surface of the base plate 3 facing away from the user. Smith teaches the steps of locating the stoma and applying the base plate and locating the inner bag liner. (Figs. 5,6) The step of attaching the receiving member 1 to the base plate is accomplished by the welding of bag liner 2 to base plate 3, as the first coupling area as disclosed includes said base plate 3 (see applicant's Abstract). (Cols. 4 and 5, all lines)

Smith teaches that inner bag liner 2 is welded to base plate 3 and thus does not teach that the bag liner 2 is reattachably attachable to the base plate 3 in a first coupling area by a first coupling component. However, Smith teaches that welding and double sided adhesive tape are equivalent means for attaching outer bag 1 to the base plate 3 and teaches that bag liner 2, not outer receiving member/bag 1, is disposed of after a single use, therefore it would be obvious to one of ordinary skill in the art to modify the article of Smith such that bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling component, i.e. the

adhesive flange projecting from the rim of said third hole with a reasonable expectation of success to provide quicker releasable attachment of the disposable single-use bag liner 2.

Smith teaches a release liner 5 protecting adhesive layer 4. Smith does not explicitly teach the step of removing a release liner covering said first coupling component. However, Smith fairly suggests an adhesive first coupling component that comprises double sided tape for reasons stated *supra* in this rejection, and it is well known in the art to provide a release liner to protect an adhesive layer from contamination that is removed just prior to use. Thus, it would be obvious to one of ordinary skill in the art to modify the method fairly suggested by Smith wherein the first coupling component is double sided adhesive tape, to include the step of removing a release liner covering said adhesive first coupling component with a reasonable expectation of success as the step of removing the liner implies the existence of such liner which prevents contamination of the adhesive first coupling component suggested by Smith.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (U.S. Patent No. 5,591,144) in view of Wolrich (U.S. Patent No. 5,423,782).

With respect to **Claim 5**: An outer diameter of the first coupling component of Smith (the adhesive flange extending from the rim of said third hole) is smaller than an inner diameter of the second coupling component 12.

Smith does not teach that the second coupling component is in the form of one or more coupling rings. Wolrich teaches an ostomy bag having a receiving member in the form of an outer bag and an inner bag liner. Wolrich teaches a second coupling component as disclosed in the form of coupling means 18 comprised of a ring-shaped flange coupling 18 that mates with ring 34, i.e. one or more coupling rings. As can be seen in Fig. 1, the outer diameter of first coupling means 46 is less than the inner diameter of first coupling means 46. ('782, Col.

5, lines 10-20) Since the structure of the articles of Smith and Wolrich are substantially identical and seek to solve a similar problem in the art (i.e. provide an ostomy waste collector having a bag and an inner liner attachable to a stoma to collect waste therefrom), it would be obvious to one of ordinary skill in the art to modify the article of Smith such that the instant second coupling means (double sided tape) is replaced by the second coupling component of Wolrich to maintain the ability of the article of Smith to releasably attach to a stoma for waste collection and easier disposal.

Allowable Subject Matter

7. The objection to claims 11 and 15-17 as being dependent upon a rejected base claim, but allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, is maintained. The reasons for indicating allowable subject matter restated from the Office action mailed November 29, 2007 solely as a courtesy to applicant.

Reasons for Indicating Allowable Subject Matter

8. The following is a statement of reasons for the indication of allowable subject matter: The following is a statement of reasons for the indication of allowable subject matter: A thorough search of the prior art of record did not disclose any reference, alone or in combination with other reference(s) that teaches or fairly suggests the following: with respect to claims 11, 16 and 17, a compacted inner bag liner compacted in the manner claimed in amended claim 7 (i.e. such that the bottom of the bag liner is adjacent the claimed third hole) and provided with a cover. The limitation "to retain the inner bag liner in said compact condition prior to use" is functional language that is given little patentable weight herein. The closest prior art is the Smith reference cited herein in combination with Boehringer et al (U.S. Patent Application Publication

No. 2004/0064132). The combination of the Smith and Boehringer references would teach or fairly suggest the claimed invention. However, there is no motivation to combine these prior art devices. With respect to claims 11 and 16, Boehringer teaches a bellows device for collecting exudates from a wound site or stoma having a cover to retain such bellows in place, however one of ordinary skill in the art would not be motivated to look to the field of endeavor that the Boehringer device concerns itself with, specifically suction-assisted wound healing. Further the cover of Boehringer does not retain the bellows in a compacted condition, as the very function of the bellows is to assist in the wound collection by expanding in response to suction force applied. The cover merely provides a closed environment for the device and the wound environment. With respect to claims 15 and 17, because Smith, either alone or in combination with Boehringer, does not teach or fairly suggest such a cover for the inner bag liner, Smith, alone or in combination with Boehringer also does not disclose or suggest the method step of securing the claimed disc-like structure in the claimed compact configuration by placing a cover on a closed end of the claimed bag liner, or the step of said cover being removed in use by automatic unfolding of said bag liner.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761